

Office Action Summary	Application No. 10/537,376	Applicant(s) KASAHARA ET AL.	
	Examiner SHUANGYI ABU ALI	Art Unit 1731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>20100429</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/02/2010 has been entered.

37 CFR 1.132

The declaration under 37 CFR 1.132 filed 06/02/2010 is insufficient to overcome the rejection of claims based upon the unexpected result as set forth in the last Office action because: 1) The data provided are not commensurate in scope with the broadly claimed invention. Claim 1 recites that the compound is heated at a temperature of 100-180 °C with a time duration of 0.1-24 hour. However, applicants only present the heating time of 12 hour. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range.

2) The prior art disclose teaches the age time can be up to 100 hour and the pH of the reaction condition is 8-10. The Examiner respectfully submits that the applicant should conduct the experiment according to the teaching of prior art. For

Art Unit: 1731

example the prior art disclose that the pH of the reaction is in range of 9-10 and the aging time is 0.1-100 hour.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 6,663,948

Regarding claims 1, 3 and 11, '948 discloses a process of making calcium phosphate substrate by reacting a calcium compound with a water soluble phosphate. The reaction pH is in the range of 8-10 at a temperature of 20-97 °C. The reaction mixture is aged for about 0.1-100 hours (col. 6, line 45-col. 7, line 5). The '948 patent

Art Unit: 1731

further disclose that the substrate further has the following properties (col. 3, lines 40-50 and table 2):

TABLE 2

Reference Examples	1	2	3	4
Support particles	M1	M2	M3	M4
Dm	0.8	1.5	4.5	25
α_m	1.2	1.7	1.4	1.2
β_m	0.6	0.8	0.8	1.0
S _m	165	150	140	120
Tm1	7.3	8.1	9.6	12.9
Tm2	3.4	3.8	4.7	9.5

Since the calcium phosphate of '948 is made by a process similar to the process for making calcium phosphate discloses in the instant invention, it is reasonably expected that calcium phosphate of '948 is substantially similar to that of the instant claims. The teaching '948 is silent about the property of calcium phosphate the set forth by applicant in claim 1. However, the property(heat loss, standard deviation, the pore diameter and the amount of the fine pore diameter of the calcium phosphate) is determined by the constituents of the composition itself, the claimed property would be necessary followed from the teaching of '948.

It is noted that claims are product-by-process claims. Eventhough product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior

Art Unit: 1731

product was made by a different process.” In re Thorpe, 77F.2d 695, 698,227 USPQ 964,966 (Fed. Cir. 1985) (citations omitted).

Regarding claim 2, '948 disclose that the dispersion coefficient can be 1.2 and the sharpness can be 0.6-1.0(table2).

Regarding claims 4 and 12 -13, '948 discloses that the phosphate has a structure of hydroxyapatite. (col. 13, lines 50-51)

Response to Arguments

Applicant's arguments filed 06/02/2010 have been fully considered but they are not persuasive.

The applicants argue that the prior art discloses the aging temperature is up to 97 °C. The Examiner respectfully submits that the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Since the prior art discloses a similar process of making calcium carbonate as that of the instant application , it is reasonably expected that calcium phosphate of '948 is substantially similar to that of the instant claims. The Applicants argue that the declaration filed on 06/02/2010 discloses the product of prior art is different from the product of the instant application. The Examiner respectfully submits that the applicant should conduct the experiment according to the teaching of prior art. For example the prior

Art Unit: 1731

art disclose that the pH of the reaction is in range of 9-10 and the aging time is 0.1-100 hour.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUANGYI ABU ALI whose telephone number is (571)272-6453. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shuangyi Abu-Ali/
Examiner, Art Unit 1731

Application/Control Number: 10/537,376
Art Unit: 1731

Page 7